

REMARKS

Entry of the foregoing, re-examination and reconsideration of the subject matter identified in caption, as amended, pursuant to and consistent with 37 C.F.R. §1.111, and in light of the remarks which follow, are respectfully requested.

By the foregoing amendment, claim 1 has been amended to include a reference to the crystals recited in step (d) as resulting from the crystallization of step (c). Support for this amendment follows from the language of the claim itself and may also be found in the specification. Claim 5 has been amended to recite "according" rather than "accordingly".

In the Official Action, claims 1-10 stand rejected under 35 U.S.C. §112, second paragraph, as being allegedly indefinite.

By the foregoing amendments, the issues mentioned in the Official Action are believed to be obviated.

Withdrawal of the second paragraph rejections is requested.

Claims 1-6 and 8-10 stand rejected under 35 U.S.C. §102(b) as being allegedly anticipated by WO 97/32644 (WO '644). In addition, claims 1, 2, 4-6 and 8-10 stand rejected as being allegedly anticipated by Reuter '259 (U.S. Patent No. 5,872,259). Applicant respectfully traverses these rejections for at least the following reasons.

WO '644 and Reuter both relate to processes for separating a desired substance from an aggregate mixture in which a three phase dispersion is formed, the first phase comprising the aggregate mixture, the second phase comprising a liquid transport phase, and the third phase comprising a surface upon which the desired substance can crystallize.

WO '644 and Reuter both fail to anticipate (or render obvious) Applicant's claimed invention at least for the reason that each and every feature of the claims is not disclosed or

suggested. For reasons more fully explained below, the processes referred to in these documents are not the same as and do not render the present claims obvious.

At the outset, it is noted that “[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). “The identical invention must be shown in as complete detail as is contained in the ... claim.” *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). The elements must be arranged as required by the claim, but this is not an *ipsissimis verbis* test, i.e., identity of terminology is not required. *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990). Note that, in some circumstances, it is permissible to use multiple references in a 35 U.S.C. 102 rejection. See MPEP § 2131.01.

In the present case, WO '644 and Reuter fail to teach or suggest, e.g., dissolving additional impure substance in the emulsion filtrate according to step (e) of claim 1. As such, Applicant's claimed process is distinct and not anticipated by the processes mentioned in these documents.

In reference to WO '644, Applicant notes that only additional substance of the type that is crystallized out is added. The impurities that do not crystallize in the emulsion crystallization process remain in constant concentration and are in equilibrium with the aggregate feed mixture (e.g., in column (3) according to Fig. 1). Only a flow of the desired substance to be crystallized out takes place, while the impurities, once equilibrium is established, remain in the crude mixture. In stark contrast, Applicant's process provides for the crystallization of desired compounds and allows for adding the aggregate mixture (i.e., both the impurities and the desired substance to be crystallized) directly into the emulsion from which crystallization takes place.

Applicant further notes that the continuous emulsion crystallization process described in WO '644 (which requires the apparatus of Fig. 1) is designed in a rather complex way with

an external column (3), filters (8) and (10) and heat exchangers (9, 9a). The purpose of this complex design is to very selectively dissolve and extract, at elevated temperature, only the desired material provided in crude form in column (3). No undissolved matter enters vessel (4) due to filtration of solids with filter (10). Therefore, only those components of the crude which can be dissolved by an undersaturated emulsion will be introduced into vessel (4) and then be depleted there by crystallization. After recycling through (9), the circulating emulsion is already saturated to equilibrium at the extraction/reloading temperature with the undesired impurities which do not crystallize out, so that no further net amounts of such impurities can be dissolved. These undesired impurities do not crystallize out in the emulsion (4) in Fig. 1 of WO '644. In contrast, the desired substance that is crystallized out in pure form in (4) can be replaced with new desired compound (e.g. enantiomer, isomer or the like) by passing the emulsion through the heat exchanger and then through column (3).

The net effect of the process of WO '644 is that the same amount of impurities is always present in dissolved form in the system (*i.e.*, no net extraction of the impurities is obtained), while only the desired substance is crystallized out in (4) and replaced with redissolved substance in column (3). A net enrichment of desired substance and net removal of desired substance out of the system in pure form results. Although not all crude material is dissolved during the extraction process, the undissolved by-products and impurities (the waste material) are carried away through exit (15), either continuously or stepwise (*i.e.*, batchwise). See, e.g., p. 17, lines 16-17 of WO '644. The net amount of impurities in dissolved form always remains the same. No out-crystallization of these impurities takes place. Instead, a net mass transport of the desired compound that is allowed to crystallize takes place from the crude to the emulsion, and from the emulsion to the crystal surface.

Stated another way, the non-crystallizing impurities in the emulsion of WO '644 are dissolved only once to such an extent that saturation-equilibrium of the circulating emulsion is achieved (e.g. in column (3) of Fig. 1). No net transport of impurities into vessel (4) takes place,

just a net (continuous or batchwise) dissolution of the desired pure substance that crystallizes out in pure form. In contrast, in Applicant's system, both impurities and the desired pure substance (*i.e.* the whole crude mixture) are dissolved repeatedly according to, *e.g.*, step (e) of claim 1. As well, Applicant's process replaces the rather complicated circulation and apparatus of, *e.g.*, WO '644 with a simplified arrangement in which both impurities and desired substances are introduced into the system. Applicant's surprisingly simplified process is thus clearly distinguished over WO '644.

As mentioned in Applicant's specification at page 1 (especially lines 27-34), continuous operation of the process of WO '644 can lead to a number of cumbersome, even highly undesirable deficiencies. For example, the equipment required is complicated, the external column and filters are susceptible to clogging, and a risk of loss of emulsion during removal of the crude material exists, to name a few. Additional difficulties with normal emulsion crystallization may also be present; for example, obtainable yields may be substantially lower than with classical (solution) crystallization due mainly to the difficulty in removing solvent from the mother liquor (which may, *e.g.*, lead to breakdown of the emulsion), and that surfactants usually cannot be distilled away in parallel to solvents. Some emulsions also cannot be loaded with impure substance in high concentrations since this would lead to emulsion instability, unworkable viscosity and/or suboptimal crystal growth (see, *e.g.*, p. 1, line 36 to p. 2, line 3 of Applicant's specification). Applicant's process, however, overcomes these disadvantages in part since additional impure substance is now dissolved directly in the emulsion filtrate, leading to improved yield and lowered costs, as well as avoiding the difficulties of operating a process according to WO '644.

Applicant notes that the foregoing arguments are also applicable against Reuter. In particular, although Reuter also describes a process for separating a desired substance from an aggregate mixture in which a three phase dispersion is formed, there is no disclosure or suggestion of dissolving additional impure substance in the emulsion filtrate according to

step (e) of claim 1. Further, while Reuter makes use of microemulsions rather than macroemulsions according to WO '644, the same reasoning applicable against WO '644 clearly establishes that Applicant's claims are also not anticipated by Reuter.

For at least the foregoing reasons, Applicant respectfully submits that the present claims are novel and patentable over WO 97/32644 and Reuter (U.S. Patent No. 5,872,259). Withdrawal of the §102 rejections is requested.

Claims 1-10 stand rejected under 35 U.S.C. §103(a) as being allegedly unpatentable over Reuter '259 in view of WO 97/32644 (WO '644) and Marsh (U.S. Patent No. 3,141,743). Claims 1-10 stand further rejected as being allegedly unpatentable over WO 97/32644 (WO '644) in view of Marsh. Applicant respectfully traverses these rejections for at least the following reasons.

At the outset, Applicant submits that the claims are allowable over Reuter and WO '644 as combined with Marsh and, separately, WO '644 combined with Marsh, for the reasons noted above in traverse of the rejections under §102 based upon WO '644 and Reuter. Applicant's arguments set forth *supra* are incorporated herein.

Marsh relates to a crystallization process for the recovery of various sulfate salts of aluminum. Washing of the obtained crystals is mentioned (column 5, line 28 et seq), which may be conducted during centrifugation.

Marsh fails to remedy the deficiencies noted above for WO '644 and Reuter, however. In particular, Marsh provides nothing to teach or suggest step (e) according to claim 1, i.e. dissolving additional impure substance in the emulsion filtrate. Instead, all Marsh appears to provide is information that centrifugation and washing of crystals is known for crystal separation. As such, the present claims are not *prima facie* obvious over the proposed combination of Reuter and/or WO '644 with Marsh.

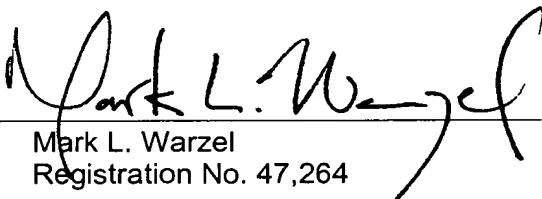
For at least the foregoing reasons, Applicant respectfully submits that the present claims are patentable over Reuter (U.S. Patent No. 5,872,259) and/or WO 97/32644 as combined with Marsh (U.S. Patent No. 3,141,743). Withdrawal of the §103 rejections is requested.

Further and favorable action in the form of a Notice of Allowance is believed to be next in order, and such action is earnestly solicited.

If any issues remain outstanding, or should the examiner have any questions concerning the foregoing amendments and remarks, a telephone call to the undersigned would be appreciated.

Respectfully submitted,
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Marked-up Version of Claims 1 and 5

1. (amended) A process for purifying an impure substance through emulsion [crystallisation] crystallization comprising the steps of

- (a) forming an emulsion of organic liquid droplets in a continuous water phase, which emulsion contains the impure substance;
- (b) super-saturating the emulsion in the substance;
- (c) inducing crystallization of the substance, whereby crystallization takes place in the water phase;
- (d) isolating the crystals of the substance resulting from step (c) from the emulsion, yielding an emulsion-filtrate;
- (e) dissolving additional impure substance in the emulsion-filtrate; and
- (f) repeating steps (b)-(d) with the emulsion obtained from step (e).

5. (twice amended) A process [accordingly] according to claim 1, wherein dissolving of additional impure substance in step (e) is carried out by ultrasound, heating and/or stirring.